UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,396	12/28/2001	Ryoichi Nagata	2001_1906A	8735

513 7590 01/09/2003

WENDEROTH, LIND & PONACK, L.L.P.
2033 K STREET N. W.
SUITE 800
WASHINGTON, DC 20006-1021

EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,396	NAGATA, RYOICHI	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002 (paper no.8)* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Amendment filed 10/15/02.

Claims 1-12 are pending. Claims 13 and 14 have been cancelled by virtue of the Amendment. Claims 1-12 remain rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yanagawa (EPO 0 681 833 A2) in view of Staniforth *et al.* (US Pat. No.5, 948,438).

Yanagawa teaches a nasally administrable composition containing a homogeneously dispersed physiologically active peptide – insulin, in combination with a crystalline metal carrier, such as calcium carbonate, to be administered via a nasal cavity in a powder formulation (see reference pages 2-4). The carrier may have a mean particle size of not more than 250 microns, or more preferably 30 microns to 60 microns (see page 3). The examples taught by Yanagawa show the use of glucagon in combination with calcium carbonate and the use of insulin with hydroxyapatite. Both examples teach the use of peptide hormones in combination with an accepted carrier (see pages 19 and 25).

Yanagawa while teaching a nasally administered composition comprising insulin and calcium carbonate does not explicitly teach the use of porous calcium carbonate in the formulation.

Staniforth et al. teach pharmaceutical formulations having improved disintegration and/or absorptivity wherein calcium carbonate is used in combination with porous particles of microcrystalline cellulose and can comprise additional active ingredients such as insulin and anti-diabetic drugs (see reference column 17, line 60 through col. 18, line 40); (col. 19, line 11). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use porous particles of calcium carbonate as a carrier because they can provide better performance and be more cost effective than various carriers. The expected result would be a highly

effective pharmaceutical formulation having improved disintegration and/or absorptivity as similarly desired by the applicant.

Response to Arguments

Applicant's arguments filed 10/15/02 have been fully considered but they are not persuasive.

Firstly, the applicant argued regarding the 35 U.S.C. 103(a) rejection of Yanagawa (EPO 0 681 833 A2) in view of Staniforth et al. (US Pat. No. 5, 948,438) that, "the porous, spherical calcium carbonate is mentioned neither in Yanagawa nor in Staniforth et al."

This argument has been fully considered but was not found to be persuasive. The instant claims are drawn to a formulation for the nasal absorbtion of insulin, which comprises a component composed of insulin and porous, spherical calcium carbonate as its carrier. The prior art of Yanagawa (EPO '833 A2) teaches a nasally administrable composition containing a homogeneously dispersed physiologically active peptide – insulin, in combination with a crystalline metal carrier, such as calcium carbonate, to be administered via a nasal cavity in a powder formulation (see reference pages 2-4). The prior art of Staniforth et al. (US '438) teaches pharmaceutical formulations having improved disintegration and/or absorptivity wherein calcium carbonate is used in combination with porous particles of microcrystalline cellulose and can comprise additional active ingredients such as insulin and anti-diabetic drugs (see reference

column 17, line 60 through col. 18, line 40); (col. 19, line 11). The applicant's assertion that porous, spherical calcium carbonate is mentioned neither in Yanagawa nor in Staniforth et al. was not found persuasive since the prior art teaches the use of a nasal composition comprising insulin and calcium carbonate as the carrier. The calcium carbonate may be in a powdery or a crystallized form (see '833 A2 pg. 4, lines 30-32). Staniforth also teaches calcium carbonate in combination with therapeutically active agents, such as antidiabetics – insulin (see col. 17, line 61 and col. 18, line 40).

Secondly, the applicant argued, "Yanagawa, however only shows that calcium carbonate is an example to be selected from among various carriers, and thus has no teaching as to give incentive for skilled persons to choose calcium carbonate whose structure, in particular internal structure, has been changed."

This argument has been fully considered, but was not found to be persuasive. The applicant admits, "Yanagawa discloses using a carrier for nasally administrable composition and a wide variety of physiologically acceptable powdery or crystalline polyvalent metal compound carriers. In this reference, the use of calcium carbonate is also mentioned." The prior art teaches a nasal composition comprising the same ingredients (insulin and calcium carbonate) for the same intended purpose as the applicants. The prior art additionally teaches a composition comprising the applicants desired particle size range of calcium carbonate and therefore similar properties as those of the instant invention would be imparted. It is of no moment that the prior art recognize each and every property exhibited by a particular component or ingredient,

merely that the prior art recognize the teaching of the ingredient itself, in a similarly formulated manner is sufficient. In this instance, Yanagawa teaches a nasal composition comprising a carrier, calcium carbonate in combination with insulin, which is ideally what the applicant is intending to claim.

Finally, the applicant argued, "Staniforth et al. give no incentive to choose such a specific calcium carbonate as the present invention" and that, "Stanifiorth et al. simply teach that "calcium carbonate" can be used as a filler if desired."

This argument has been fully considered, but was not found to be persuasive since Staniforth teaches the use of calcium carbonate in combination with active ingredients, such as insulin and anti-diabetic drugs (see cols. 17-19). Staniforth teaches a composition comprising the same basic ingredients required as those of the instant invention. There is no significant difference observed between the prior art and the instant invention since Staniforth teaches a pharmaceutical formulation, which contains the desired components as claimed by the applicant. The applicants assertion that calcium carbonate may be used as a filler in the final product, is not seen as critical because the prior art does in fact teach the ingredient, calcium carbonate in combination with active agents, such as insulin and anti-diabetic drugs, whereby the teaching alone of calcium carbonate alone, is sufficient and relevant.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600